SPECIAL 510(k): Device Modification
OIVD Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER: k121492

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
   Beckman Coulter Incorporation, Synchron® Systems Hemoglobin A1c Reagent (k010748)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the FUNDAMENTAL **SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for:

   1. Reagent re-formulation including addition of different buffers
   2. Reagent and sample volumes.
   3. The measuring range was changed from 2 to 20% to 4 to 17%.
   4. Report LoB and LoD values in the labeling.
   5. The HbA1c- is reported in NGSP% units and mmol/mol IFCC units.
   6. The stability claim for the opened Hb reagent vial changed from 60 days to 30 days when stored at 2 to 8 ºC.
   7. The stability claim for the opened calibrators changed from 90 days to 60 days when stored at -15 to -20 ºC. The stability claim for the frozen aliquots of the calibrators to freeze/thaw cycles changed from four cycles to one cycle.
   8. Calibrator level 1 is changed from zero to non-zero low concentration level.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance test.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular

modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Shirin M. Marfatia (Reviewer's Signature) 09-10-2012 (Date)

Comments

1) The submission was received on May 21, 2012, and was placed on telephone hold twice (June 08, 2012 and August 03, 2012).
2) The sponsor provided complete response on September 07, 2012. Based on the response, I recommend a SE determination.
3) The following information for LCP product code was found in the post-market database:
   a) Two Gen Docs.
   b) Seventy MDRs including 6 injury/death, 11 patient problems, 22 device problems, 14 recalls, and 3 inspections and EIRs.
   c) The sponsor Beckman Coulter specifically had one class II recall.
4) The labeling for this modified subject device has been reviewed to verify that the indications/intended use for the device is unaffected by the modifications. In addition, the submitter's description of the particular modifications and the comparative information between the modified and the unmodified devices demonstrate that the fundamental scientific technology has not changed.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	x		If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: CS

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

   Descriptive characteristics are not adequate to make a determination of substantial equivalence for an IVD. Performance data must be characterized and compared to the predicate device or a reference method.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

   The performance data obtained from the verification/validation activities using pre-determined acceptance criteria were acceptable for an *in vitro* diagnostic device for this intended use. In conclusion, the reviewed information demonstrates that the device is substantially equivalent.